

SUBJECT: ALLERGY TESTING

POLICY NUMBER: 2.01.10

CATEGORY: Technology Assessment

EFFECTIVE DATE: 01/20/00

REVISED DATE: 10/18/01, 10/16/02, 10/15/03, 09/16/04, 11/17/05, 09/21/06, 12/20/07, 09/18/08, 09/17/09, 09/16/10, 09/15/11, 09/20/12, 09/19/13, 09/18/14

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- *If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.*
- *Medical policies apply to commercial and Medicaid products only when a contract benefit for the specific service exists.*
- *Medical policies only apply to Medicare products when a contract benefit exists and where there are no National or Local Medicare coverage decisions for the specific service.*

POLICY STATEMENT:

Based upon our criteria and review of the peer-reviewed literature, the following tests are **medically appropriate** in the diagnosis of the allergic patient:

CODE	DESCRIPTION	GUIDELINE
95004	Percutaneous tests (scratch, puncture, prick) with allergenic extracts, immediate type reaction, including test interpretation and report, specify number of tests	The number of tests required may vary widely from patient to patient, depending upon the patient's history, and may require up to 70 tests.
95017	Allergy testing, any combination of percutaneous (scratch, puncture, prick) and intracutaneous (intradermal), sequential and incremental, with venoms, immediate type reaction, including test interpretation and report, specify number of tests (considered investigational for serial endpoint testing)	
95018	Allergy testing, any combination of percutaneous (scratch, puncture, prick) and intracutaneous (intradermal), sequential and incremental, with drugs or biologicals, immediate type reaction, including test interpretation and report, specify number of tests (considered investigational for serial endpoint testing)	Usually used when percutaneous testing is not considered to be sensitive enough to the cause of an allergic reaction. The number of tests required may vary widely from patient to patient, depending upon the patient's history, and may require up to 40 tests.
95024	Intracutaneous (intradermal) tests with allergenic extracts, immediate type reaction, including test interpretation and report, specify number of tests	
95028	Intracutaneous (intradermal) tests with allergenic extracts, delayed type reaction, including reading, specify number of tests	Used as a part of an evaluation of the status of immune function. The number of tests is usually small, under 10 tests.
95044	Patch or application test(s) (specify number of tests)	Also known as delayed hypersensitivity testing, this testing modality identifies allergens causing contact dermatitis. The suspected allergens are applied to the patient's back under dressings and allowed to remain in contact with the skin for 48 to 72 hours. The area is then examined for evidence of delayed hypersensitivity reactions.

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CODE	DESCRIPTION	GUIDELINE
95052	Photo patch test(s) (specify number of tests)	This test reflects contact photosensitization. A patch of skin is applied with the suspected sensitizer for 48 hours. If no reaction occurs, the area is exposed to a dose of ultraviolet light sufficient to produce inflammatory redness of the skin. If the test is positive, a more severe reaction develops at the patch site than on the surrounding skin.
95056	Photo tests	Photo, or photosensitivity, tests are performed for the evaluation of photosensitivity disorders by irradiating the skin with a specified range of ultraviolet light.
95070	Inhalation bronchial challenge testing (not including necessary pulmonary function tests); with histamine, methacholine, or similar compounds	Histamine or methacholine is used to perform this test when it is necessary to determine if the patient has hyper-responsive airways. Volatile chemicals are used to perform the test when the allergy is encountered in an occupational setting. If dust, ragweed or other common allergens are the suspected cause of the problem, this test is not medically appropriate since skin tests can be used in these situations.
95071	Inhalation bronchial challenge testing (not including necessary pulmonary function tests); with antigens or gases, specify	
95076	Ingestion challenge test (sequential and incremental ingestion of test items, eg, food, drug or other substance); initial 120 minutes of testing	With these tests the patient ingests a food, drug or other substance to which sensitivity is suspected. This may be done in an open or blinded manner. Testing may be done at home, but in some instances of extreme suspected hypersensitivity, it may be performed in the office setting.
95079	Ingestion challenge test (sequential and incremental ingestion of test items, eg, food, drug or other substance); initial 120 minutes of testing; each additional 60 minutes of testing	
82785	Gammaglobulin (immunoglobulin), IgE	Total serum IgE concentration testing is not indicated in most allergic patients, but may be indicated for patients suspected of having allergic bronchopulmonary aspergillosis, immune deficiency disease characterized by increased IgE levels (e.g., Wiskott-Aldrich syndrome, hyper-IgE staphylococcal abscess syndrome), IgE myeloma, pemphigoid, or a poorly controlled moderate to severe asthmatic patient being considered for possible anti IgE treatment.
86001	Allergen specific IgG; quantitative or semiquantitative, each allergen	Commonly known as RAST (radioallergosorbent) testing, these tests detect antigen-specific IgG antibodies in the patient's serum and are medically appropriate only in testing for insect venoms in patients allergic to insect stings.

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CODE	DESCRIPTION	GUIDELINE
86003	Allergen specific IgE; quantitative or semiquantitative, each allergen	Commonly known as RAST (radioallergosorbent) testing, these tests detect antigen-specific IgE antibodies in the patient's serum. They are medically appropriate only when testing for allergens (e.g., inhalant, food, insect, drug): I. When direct skin testing is impossible due to extensive dermatitis or marked dermatographism; II. For patients unable to discontinue use of interfering medications (e.g., antidepressants, antihistamines, or beta blocking agents); III. For those who have had a near fatal reaction to an allergen; IV. In children less than four years of age; V. In patients who will not or cannot cooperate with percutaneous testing due to mental or physical disease (e.g., Down syndrome, mental retardation, dementia); VI. To follow patients with food allergies and/or insect sting allergies previously documented by history and in-vivo or in-vitro testing; VII. For patients with suspected latex allergy; VIII. For patients with suspected insect sting allergy in the face of negative skin testing; or IX. For patients with suspected penicillin allergy.
86005	Allergen specific IgE; qualitative, multi-allergen screen (dipstick, paddle or disk)	

Based upon our criteria and review of the peer-reviewed literature, the following allergy tests have not been medically proven to be effective and are considered **investigational**:

CODE	DESCRIPTION
86343	Leukocyte histamine release test (LHR)
95027	Intracutaneous (intradermal) tests, sequential and incremental, with allergenic extracts for airborne allergens, immediate type reaction, including test interpretation and report, specify number of tests (<i>Code utilized for serial endpoint testing</i>)
95060	Ophthalmic mucous membrane test
95065	Direct nasal mucous membrane test
No specific code(s)	Cytotoxicity, Provocative testing (e.g., Rinkel test), Re buck skin window test.

Refer to Corporate Medical Policy #2.01.04 regarding Clinical Ecology/Multiple Chemical Sensitivities/Idiopathic Environmental Intolerance.

Refer to Corporate Medical Policy # 2.01.11 regarding Allergen Immunotherapy.

Refer to Corporate Medical Policy # 11.01.03 regarding Experimental and Investigational Services.

POLICY GUIDELINES:

The Federal Employees Health Benefit Program (FEHBP/FEPP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

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DESCRIPTION:

Allergic or hypersensitivity disorders may be manifested by generalized systemic reactions as well as localized reactions in any organ system of the body. The reactions may be acute, subacute or chronic, immediate or delayed and may be caused by numerous offending agents (e.g., pollen, molds, dust, mites, animal dander, stinging insect venoms, foods and drugs).

The optimum management of the allergic patient should include a careful history and physical examination and may include confirming the cause of allergic reaction by information from various testing methods as outlined below. Once the offending allergenic agent(s) are identified treatment is provided by avoidance, medication and/or immunotherapy.

RATIONALE:

Although *in vivo* (e.g., percutaneous, intracutaneous) testing is presently the preferred method of diagnostic allergy testing for IgE mediated sensitivity *in vitro* (e.g., RAST) tests are useful when used as stated in the situations identified in the above table.

According to a November 2006 American Academy of Allergy, Asthma and Immunology work group report addressing Allergy Diagnosis in Clinical Practice IgE antibody assay technology has improved with new high binding capacity solid phase matrices, non-isotopic labels for detection antibodies and standards calibrated to the World Health Organization IgE reference preparation. These enhancements have led to an evolution in assay methods from the first generation qualitative assays (e.g., RAST, MAST, EAST), through the second generation semi-quantitative IgE assays (e.g., AutoCAP, Alastat, HYTech, Matrix, MagicLite), to the present state-of-the-art quantitative third generation autoanalyzers. Two third generation immunoassays are the ImmunoCAP System (Phadia) and the Immulite 2000 (Diagnostic Products Corp) whose chemistry is similar to the original RAST, but employ non-isotopic labels and have more rapid throughput with improved precision, accuracy and analytical sensitivity. Their automated chemistries report out allergen-specific IgE antibody quantitatively.

Serial endpoint testing (SET), or intradermal dilutional testing (IDT), is a form of intradermal skin testing that uses increasing doses of antigen to determine the concentration at which the reaction changes from negative to positive (the “endpoint”). The test has been used for diagnosing allergic disorders and to guide the initiation of immunotherapy by using the endpoint dilution as the starting antigen dose. Many limitations exist in the published literature addressing SET. Sufficient conclusions on whether SET improves health outcomes as compared to standard immunotherapy or whether it is as beneficial as established alternatives cannot be made.

Leukocyte histamine release testing (LHRT) is a technique to evaluate the *in vitro* release of histamine from leukocytes in response to an allergen and provide an *in vitro* correlate to an *in vivo* allergic response. Published literature regarding the commercially available LHRTs suffers from not having been performed in a blinded manner or not indicating whether or not there were blinded interpretations of the tests. Some studies included patients with known allergies, which do not represent the same population with equivocal allergy histories that would undergo testing. Studies of LHRT are potentially prone to spectrum, referral, and ascertainment bias, and are not sufficient to permit conclusions on the diagnostic accuracy of the tests. It has been suggested that LHRT may be a valuable test in those patients with discordant results of skin prick testing and RAST testing, but studies focusing on this subgroup of patients have not been identified.

A number of procedures have been shown to be invalid for any clinical purpose. Studies of *cytotoxic tests* and *provocation-neutralization tests* have demonstrated that results are not reproducible. *Electrodermal diagnosis* and *applied kinesiology* have not been evaluated for efficacy. The “*reaginic*” *pulse test* and *chemical analysis of body tissues* have not been substantiated as valid allergy tests. These tests are considered to be investigational.

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CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

CPT: Refer to the tables in the policy statement section.

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HCPCS: No code(s)

<u>ICD9:</u>	117.3 Aspergillosis (allergic bronchopulmonary)
	279.03 Immune deficiency disease (IgE)
	279.12 Wiskott-Aldrich syndrome
	372.14 Other chronic allergic conjunctivitis
	477 Allergic rhinitis
	477.0 due to pollen
	477.1 due to food
	477.2 due to animal (cat) (dog) hair and dander
	477.8 due to other allergen
	477.9 cause unspecified
	493.0 Extrinsic asthma
	493.9 Asthma, unspecified
	692 Contact dermatitis
	692.0 - .6 due to contact with detergents, oils, greases, solvents, drugs, medicines, chemical products, food and plants
	692.81 due to contact with cosmetics
	692.83 due to metal
	692.84 due to animal (cat) (dog) dander
	692.89 due to other causes
	692.9 unspecified cause
	693 Dermatitis due to substances taken internally
	693.0 due to drugs and medicines
	693.1 due to food
	693.8 due to other specified substance taken internally
	693.9 due to other specified substance taken internally
	708.0 Allergic urticaria

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708.3	Dermatographia urticaria
989.5	Toxic effects of other substances, chiefly non-medicinal as to source, venom
989.82	latex
995.0 - .4	Certain adverse effects not elsewhere classified (code range)
995.6 - .69	Anaphylactic shock due to adverse food reaction (code range)
V15.0 -.09	Allergy, other than to medicinal agents (code range)
ICD10:	
B44.0-B44.9	Aspergillosis (code range)
B48.4	Penicillosis
D80.3	Selective deficiency of immunoglobulin G (IgG) subclasses
D82.0	Wiskott-Aldrich syndrome
H10.411-H10.419	Chronic giant papillary conjunctivitis (code range)
H10.45	Other chronic allergic conjunctivitis
J30.0	Vasomotor rhinitis
J30.1-J30.9	Allergic rhinitis (code range)
J45.20-J45.909	Asthma (code range)
J45.998	Other asthma
L23.0-L23.9	Allergic contact dermatitis (code range)
L24.0-L24.9	Irritant contact dermatitis (code range)
L25.0-L25.9	Unspecified contact dermatitis (code range)
L27.0-L27.9	Dermatitis due to substances taken internally (code range)
L30.0	Nummular dermatitis
L30.2	Cutaneous autosensitization
L30.8	Other specified dermatitis
L30.9	Dermatitis, unspecified
L50.0	Allergic urticaria
L50.3	Dermatographic urticaria
T36.0x5A-T50.Z95A	Poisoning by, adverse effects of & underdosing of drugs meds & biological substances (code range)
T63.001A-T63.94A	Toxic effect of contact with venomous animals and plants (code range)
T65.811A-T65.814A	Toxic effect of latex (code range)
T78.00XA-T78.09XA	Anaphylactic reaction (code range)
T78.2xxA	Anaphylactic shock, unspecified, initial encounter
T78.3xxA	Angioneurotic edema, initial encounter
T78.40XA	Allergy, unspecified, initial encounter

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T78.41xA	Arthus phenomenon, initial encounter
T78.49xA	Other allergy, initial encounter
T88.2xxA	Shock due to anesthesia, initial encounter
T88.52XA	Failed moderate sedation during procedure, initial encounter
T88.59xA	Other complications of anesthesia, initial encounter
T88.6XXA	Anaphylactic reaction due to adverse effect of correct drug or medicament properly administered, initial encounter
Z91.010-Z91.09	Allergy status other than drugs & biologicals (code range)

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*key article

KEY WORDS:

Allergy tests: Allergen specific IgE, Allergen specific IgG, Challenge, Cytotoxic, Dipstick, Disk, Intracutaneous, Intradermal, Leukocyte histamine release, Mucous membrane, Paddle, Percutaneous, Phadiatop, Prick, Provocation-neutralization, RAST, Rinkel, Scratch, Serial endpoint titration, Skin test.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) addressing Food Allergy Testing and Treatment and a Local Coverage Determination addressing RAST Type Tests. Please refer to the following websites for Medicare Members:

NCD:

https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDID=266&ncdver=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York++Upstate&KeyWord=allergy+testing&KeyWordLookUp=Title&KeyWordSearchType=And&ncd_id=110.11&ncd_version=1&basket=ncd%25253A110%25252E11%25253A1%25253AFood+Allergy+Testing+and+Treatment&bc=gAAAAA BAAAAAA&

LCD:

http://apps.ngsmedicare.com/lcd/LCD_L28463.htm